



10-29-02

1652

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ley et al.
Serial No.: 09/884,767
Filed: June 19, 2001
Entitled: NOVEL ENTERONKINASE CLEAVAGE SEQUENCES

Examiner: Charles L. Patterson Jr.

Art Unit: 1652

Attorney Docket No.: DYX-012.1 US

Commissioner for Patents
Washington, D.C. 20231

RECEIVED
OCT 31 2002
TECH CENTER 1600/2900

TRANSMITTAL LETTER

Sir:

Transmitted herewith are: [X] Response to Election/Restriction Requirement; and [X] a return postcard.

FEE FOR ADDITIONAL CLAIMS

[X] A fee for additional claims is not required.

[] A fee for additional claims is required. The additional fee has been calculated as shown below:

	TOTAL CLAIMS	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE	FEES DUE
TOTAL CLAIMS	---	---	0	× \$---	= 0.00
INDEPENDENT	---	---	0	× \$---	= 0.00
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM				+\$---	= 0.00
TOTAL FEES DUE					= 00.00

[] Small entity status has already been established for Applicant(s) in this case.

PAYMENT OF ADDITIONAL FEES[X] A check in the amount of \$ 0.00 in payment of the fee for the Restriction Requirement fee is transmitted herewith.[] A check including the amount of \$ 00.00 in payment of the fee under 37 CFR §1.18(a) for issuing an original patent.[] A check including the amount of \$ 00.00 in payment of the fee under 37 CFR §1.19(a)(1)(i) for 0 printed copies of patent charged at \$3.00 per copy.

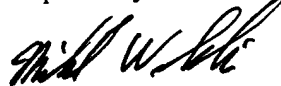
[X] The Commissioner is hereby authorized to charge payment of any additional fees required under 37 CFR 1.16 or 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to

Deposit Account No. 50-0268 . A duplicate copy of this transmittal letter is transmitted herewith.

PETITION FOR EXTENSION OF TIME

- [] Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the paper(s) filed herewith: [] \$55.00 for response within first month pursuant to 37 CFR 1.17(a)(1);
[] \$190.00 for response within second month pursuant to 37 CFR 1.17(a)(2);
[] \$435.00 for response within third month pursuant to 37 CFR 1.17(a)(3);
[] \$680.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4).
[] \$925.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).
- [X] Total amount of payment in connection with the paper(s) transmitted herewith is \$475.00.
{check no. 2357}
- [X] The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 50-0268 .

Respectfully submitted,



Michael Wesolowski; Reg. No. 50,944
Leon R. Yankwich; Reg. No. 30,237
Attorneys for Applicants
YANKWICH & ASSOCIATES
201 Broadway
Cambridge, Massachusetts 02139
telephone: (617)374-3700
telefax: (617) 374-0055

CERTIFICATE OF MAILING

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service as Express Mail, in an envelope addressed to the Commissioner for Patents, Washington, DC 20231, on the date indicated below.

October 28, 2002
Date

Melanie A. McFadden
Melanie A. McFadden



49
LPP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : LEY et al.

Serial No. : 09/884,767

Filed : June 19, 2001

Entitled : NOVEL ENTEROKINASE CLEAVAGE
SEQUENCES

ART UNIT: 1652

EXAMINER: Patterson, C.

Atty. Docket No.: DYX-012.1 US

Commissioner for Patents
Washington, DC 20231

RECEIVED

OCT 31 2002

TECH CENTER 1600/2900

EXPRESS ELECTION AND TRAVERSE UNDER 37 CFR §1.143

Sir:

In response to the Office Action dated September 26, 2002 requiring election among the restricted groups of invention, Applicants elect Group I with traverse and additionally request reconsideration and withdrawal of the requirement of restriction for the reasons set forth below.

The original response date to the Office Action, October 26, 2002, fell on a Saturday, thereby making the response deadline Monday, October 28, 2002.

In the Office Action at page 2, paragraph 1, the Examiner has presented a 194-way restriction of Applicants' invention, as between:

- Group 1 (claims 1-7), drawn to a polypeptide comprising an EK recognition site having the formula:
Z₁-Xaa₁-Xaa₂-Xaa₃-Xaa₄-Asp-Arg-Xaa₅-Z₂ (SEQ ID NO:1);
- Group 2 (claims 8-12), drawn to a polypeptide comprising an EK recognition site having the formula:
Z₁-Xaa₁-Xaa₂-Xaa₃-Xaa₄-Glu-Arg-Xaa₅-Z₂ (SEQ ID NO:2);
- Groups 3-185 (claim 13), drawn to a polypeptide comprising an EK recognition site having a sequence selected from:
SEQ ID NO: 10-73 and 75-193, (the Examiner considers each sequence a separate invention and thus a distinct restriction group);
- Group 186 (claims 14-20), drawn to a polynucleotide encoding an EK-cleavable fusion protein comprising the formula:
Asp-Ile-Asn-Asp-Asp-Arg (SEQ ID NO:208), and a vector and host cell;
- Group 187 (claims 14-20), drawn to a polynucleotide encoding an EK-cleavable fusion protein comprising the formula:

Gly-Asn-Tyr-Thr-Asp-Arg (SEQ ID NO:209), and a vector and host cell;

- Group 188 (claims 21-24, 26), drawn to a method for isolating a protein of interest comprising culturing a host cell expressing SEQ ID NO: 1 or 206;
- Group 189 (claims 21-23, 25), drawn to a method for isolating a protein of interest comprising culturing a host cell expressing SEQ ID NO: 2 or 207;
- Group 190 (claims 27-35), drawn to a method for isolating a genetic package expressing SEQ ID NO: 213;
- Group 191 (claims 27-35), drawn to a method for isolating a genetic package expressing SEQ ID NO: 215;
- Group 192 (claims 27-35), drawn to a method for isolating a genetic package expressing SEQ ID NO: 217;
- Group 193 (claims 36-43), drawn to a method for controlling the activity of a protein of interest; and
- Group 194 (claims 44-49), drawn to a method of selecting display polypeptides from a display library.

The Examiner reasons as follows: "Groups (1-185) are drawn to different chemical compounds from groups (186 and 187) and are patentably distinct. The methods of groups 188-194 accomplish different things and the steps are different, and therefore they are patentably distinct." (Office Action, page 3, paragraph 5) Applicants traverse this requirement and request consideration of all claims together in this application, for the reasons set forth below.

The present invention relates to the discovery and use of novel enterokinase recognition sequences and to methods that flow naturally from such discovery.

The Examiner's original grouping of the claims indicates that each of the 183 separate polypeptide embodiments described in the application and recited in claim 13 has been regarded as a separate invention that must be prosecuted separately, as has every use of such polypeptides as defined in the claims. However, because the embodiments of the invention share common features, fractionation of the claims as required in the Office Action would lead to unnecessarily repetitive examination and an unfairly protracted and expensive series of related applications to be filed by Applicants to obtain the patent protection to which they are entitled.

In addition, as explained in the specification, most of the enterokinase recognition sequences share one or more sequence motifs, such as Z_1 -Xaa₁-Xaa₂-Xaa₃-Xaa₄-Asp-Arg-Xaa₅-Z₂ (SEQ ID NO:1) or Z_1 -Xaa₁-Xaa₂-Xaa₃-Xaa₄-Glu-Arg-Xaa₅-Z₂ (SEQ ID NO:2). Therefore, each peptide sequence of claim 13 should not be considered separately because many of the peptides

are included in Group I and II. Moreover, they are not unrelated sequences; they are all EK-cleavable peptides and share certain structural features explained in the specification.

In view of these common features, it is seen that all of the polypeptide structures recited in the claims may be efficiently searched together, without placing an undue burden on the Examiner.

In addition to the claims reciting enterokinase recognition sequences, claims 27 -33, directed to a method for isolating a genetic package of interest, are not specific to any particular sequence, and therefore they should not be restricted into three groups, i.e., 190, 191, and 192. (Applicants note that SEQ ID Nos: 213, 215, and 217, specified in Claim 34 are not EK-cleavage sequences.)

Classification

In the Office Action (page 3, paragraph 6) the Examiner asserts that the present application contains distinct inventions that have acquired a separate status in the art, as shown by their different classification. Applicants disagree.

Proper restriction between distinct inventions claimed in the same application requires (1) that the inventions must be independent and distinct as claimed *and* (2) that there must be a serious burden placed on the Examiner by *not* requiring restriction. If either criterion is not met, restriction is not proper. MPEP §803.

Applicants note that Groups 1, 2, 3-185, and 190-192 of the present invention are provisionally classified in one class, i.e. Class 530, subclass 329 (groups 190-192 classified as subclass 344). There are many situations where claims are permissibly drafted to include a reference to more than one statutory class of invention (MPEP §2173.05(p)). In the present case, from the discussion above it is clear that the subject matter of the original claims cannot properly be divided into distinct inventions due to the interrelatedness of the subject matter as claimed. Additionally, the claims are of the type that may be examined together pursuant to 37 CFR §1.141(b). Finally, in view of the initial classification and the way in which the claims are worded, Applicants submit that the search of any of the polypeptide claim groups, Groups 1-185, would reveal the same art that is relevant to the other groups, and therefore no serious burden is on the Examiner if a restriction is not made. Instead, the burden will be on the Applicants, who will be required to exponentially increase their expenses to address the same search before full patent protection of their original invention is obtained.

For the reasons set forth above, Applicants respectfully submit that the claims as grouped for restriction by the Examiner do not represent separate or distinct inventions, and the search of

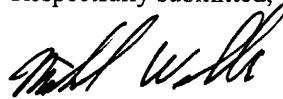
all claims together in one application would not place a serious burden on the Examiner.
Accordingly, withdrawal of the restriction requirement is requested.

Conclusion and Provisional Election

Applicants submit that in view of the foregoing remarks all the claims as originally filed are seen to relate to a single inventive concept, and the claims are in a form and are of the sort that is properly viewed as relating to a single invention that should not be restricted, under the provisions of 37 CFR §1.141(b). Applicants earnestly request that the restriction and election requirements of the Office Action of September 26, 2002 be reconsidered and withdrawn.

Although, for reasons set forth above, Applicants believe that the restriction is improper and uncalled for, and without in any way acquiescing in the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicants provisionally elect for examination the claims of Group I, i.e., claims 1-7. For the reasons set forth above, Applicants believe Claim 13, at least, should be counted as part of Group I.

Respectfully submitted,



Leon R. Yankwich, Reg. No. 30,237
Michael R. Wesolowski, Reg. No. 50,944
Applicants' Representatives
YANKWICH & ASSOCIATES
201 Broadway
Cambridge, Massachusetts 02139
telephone: 617-374-3700
telecopier: 617-374-0055

Certificate of Express Mailing

The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10, postage prepaid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on the date indicated below.

October 28, 2002
date

Melanie A. McFadden
Melanie A. McFadden

Express Mail Label No.:

EV191278664US